

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES S.A AND
DR. REDDY'S LABORATORIES, INC.,

Petitioners,

v.

EYE THERAPIES, LLC,

Patent Owner.

Case No. IPR2024-00563
U.S. Patent No. 11,596,600

DECLARATION OF JOHN FERRIS

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I, John Ferris, declare as follows:

I. INTRODUCTION

1. I have been asked to submit this declaration on behalf of Bausch's partner, Eye Therapies, LLC ("Eye Therapies" or "Patent Owner"), which I understand is being submitted in support of the Patent Owner's Response in connection with IPR2024-00563.

2. I have personal knowledge of the facts set forth herein.

3. I am currently Executive Vice President, US/Canada Consumer within the Bausch + Lomb family of companies ("Bausch"). My employment at Bausch began in 2011 in a role related to marketing of over-the-counter (OTC) eye vitamins. Over the years, I have held various roles and titles, with my current responsibilities starting in June 2023. Before that, I held the role of Senior Vice President, Global Consumer starting in January 2022. Prior to joining Bausch, I held marketing, sales, and commercial leadership positions of increasing responsibility over 15 years with Wyeth Consumer Health and Pharmaceuticals and Becton Dickinson.

4. In my current capacity of EVP, I have 6 direct reports, with a total commercial organization of almost 80 marketing, sales, and related professionals across the US and Canada. In my current role as well as my prior role of SVP, Global Consumer, I oversee all marketing and commercial efforts related to Lumify and have responsibility for the same. In this capacity, I have personal knowledge related

to Lumify-related finances, marketing, sales, and promotional material, among other things. For example, I have actively participated in meetings of the Bausch promotional review committee (“PRC”)¹ for products within my responsibility, such as Lumify eye drops.

II. DISCUSSION

A. Lumify Is a #1 Doctor Recommended and Award-Winning Brand

5. Lumify (brimonidine tartrate ophthalmic solution, 0.025%) is the first and only OTC eye drop developed with low-dose brimonidine tartrate for the treatment of ocular redness due to minor eye irritation. It is backed by multiple clinical trials with hundreds of patients, and works differently than other redness relievers.

6. Lumify’s success speaks for itself: It is the #1 doctor recommended redness relieving drop, and has received multiple awards and recognitions since launch, including:

- 2018:
 - The Zoe Report: Best Affordable Beauty Winner
 - New You: The Eyes Have It

[REDACTED]

[REDACTED]

[REDACTED]

- NACDS Product of the Year
- 2019:
 - Brides: The Best of Beauty (Eyes)
 - New Beauty: Best Innovations
- 2020: “Superstar” category of Nielsen BASES’ Top 25 Breakthrough Innovations List.
- 2021: Into the Gloss: Top 25: Cheap Thrills
- 2022:
 - New Beauty Magazine Beauty Awards: “Never Knew We Needed”
 - Glamour: “Best Beauty Innovators of 2022”
- 2023: New Beauty “Best Brightening Eye Drops”
- 2024: One of Pookie’s² Top Amazon Prime Day Recommendations

(See EX-2052, EX-2053, EX-2054, EX-2055, EX-2056, EX-2057, EX-2058, EX-2059, EX-2060, EX-2061, EX-2062.) Lumify has also been featured in numerous unsolicited national media pieces since its launch, including a spot on ABC’s *Good Morning America* and mentions in publications as wide-ranging as *The Wall Street Journal*, *Us Magazine*, *Cosmopolitan*, and *The New York Post*. EX-2063 at 3.

7. Lumify has been and continues to be a groundbreaking redness relieving option for a variety of patients, effectively setting a new standard of care in the field. Among Eye Care Professionals (ECPs), including Optometrists and Ophthalmologists, as stated above, Lumify very quickly became their #1

² “Pookie” is the TikTok persona of Campbell Hunt Puckett, a highly influential social media influencer with several million followers across her various social media accounts.

recommended brand of redness reliever. Prior to Lumify, existing redness relievers were known to have common side effects, which made ECPs hesitant to recommend them—in fact, *less than 10%* of ECPs recommended *any* redness relievers to their patients. Since the launch of Lumify, that number has grown to *76% of ECPs recommending redness relievers* with *93% of those recommendations being for Lumify*. EX-2064 at 2.

B. Lumify's Commercial Strategy Centers on Redness Reduction Using Low-Dose Brimonidine

8. Since its launch, the commercial strategy for Lumify has consistently centered on the product's unique ability to reduce eye redness, helping eyes look whiter and brighter to reveal their natural beauty. All marketing, promotional, and sales materials tie back to the FDA-approved indication for *reducing eye redness*.

9. Promoting Lumify drops for reduction of eye redness is—quite simply—required. As background, the pharmaceutical industry is highly regulated. One of the core components of this regulation relates to *on-* versus *off-* label promotion. Although I am not a lawyer, as a person with a career in marketing, I am aware of and highly sensitive to the fact that pharmaceutical products, like Lumify eye drops, must be promoted *on-label*, meaning they can only be promoted with claims consistent with the approved product labeling. Penalties for anything else (i.e., off-label promotion) are severe. For that reason, we at Bausch hold

ourselves to a very high standard in ensuring that our promotional efforts are consistent with the approved product label.

10. The FDA-approved indication for Lumify eye drops is reducing eye redness caused by minor eye irritation. Every piece of promotional content has been (and will continue to be) reviewed by Bausch PRC to ensure consistency with this approved indication. Promotion consistent with the label (i.e., on-label promotion) is a strict standard that Bausch lives by—to the extent the commercial team would attempt to do something different (i.e., to use “off-label” material), such material would *not* be approved for circulation by the Bausch PRC. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] our promotional material and commercial efforts for Lumify eye drops have been consistent with its FDA-approved indication of reducing eye redness.

11. The fact that the promotional materials for Lumify eye drops are centered on redness reduction is easy to verify. For example, below are screenshots from the Lumify consumer website (<http://www.lumifyeyes.com/products/redness-reliever-eye-drops/>), a PDF of which is also provided as EX-2065:

Redness Reliever

LUMIFY EYE DROPS

LUMIFY redness reliever eye drops significantly reduce redness to help eyes look whiter and brighter, revealing your eyes' natural beauty. Works in 1 minute.

[Get Coupon](#) [Drug Facts](#)

BUY NOW



Unique patented
formulation



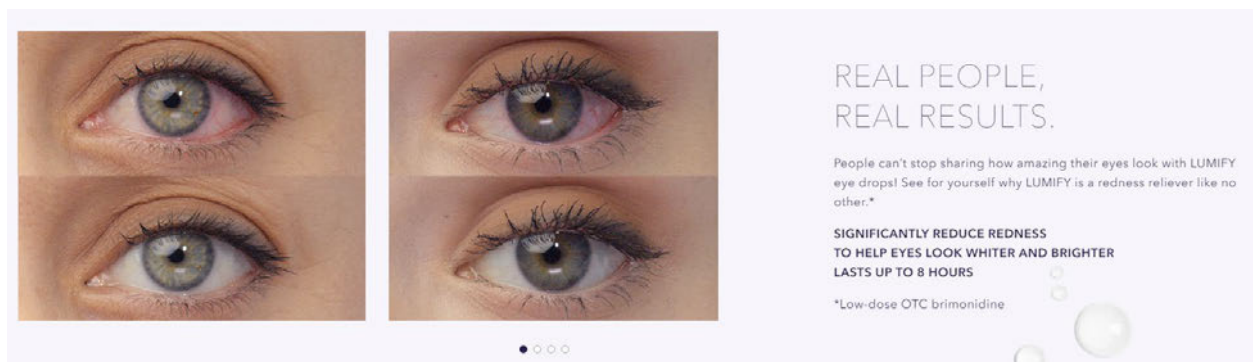
Clinically tested



#1 Eye doctor
recommended
redness reliever eye
drop



Overview	Use
- Unique, FDA-approved formulation uses low-dose brimonidine to selectively target redness - Works in just 60 seconds and lasts up to 8 hours - Lower risk of side effects like rebound redness when used as directed - Absolutely no bleach or dyes - #1 eye doctor recommended redness reliever eye drop	Relieves redness of the eye due to minor eye irritations
Full Ingredients List	Direction
Active ingredient: Brimonidine tartrate (0.025%) - redness reliever Inactive ingredients: Benzalkonium chloride, boric acid, calcium chloride dihydrate, glycerin, potassium chloride, sodium borate decahydrate, sodium chloride, water for injection. Hydrochloric acid and/or sodium hydroxide may be used to adjust pH. Drug Facts	Adults and children 5 years of age and over: - Instill 1 drop in the affected eye(s) every 6-8 hours - Do not use more than 4 times daily - Remove contact lenses before use - Wait at least 10 minutes before reinserting contact lenses after use - If using other ophthalmic products while using this product wait at least 5 minutes between each product - To avoid contamination, do not touch tip of container to any surface - Replace cap after each use Children under 5 years of age: consult a doctor



12. But it does not end there. The consumer website also offers a section called *The Science of Lumify* that centers on this same educational material. For example, below are screenshots from *The Science of Lumify* portion of the Lumify website (<https://www.lumifyeyes.com/products/redness-reliever-eye-drops/science/>), a PDF of which is also provided as EX-2066:



LUMIFY IS A ONE-OF-A-KIND EYE DROP.*

Before LUMIFY, redness relievers pretty much used the same ingredients for decades, and they had certain side effects. But then there was a break-through: eye doctors figured out that low-dose brimonidine tartrate could help relieve redness with a lower risk of certain side effects when used as directed. That's how low-dose brimonidine became the star ingredient in LUMIFY - and your little secret for amazing-looking eyes.

See the Drug Facts

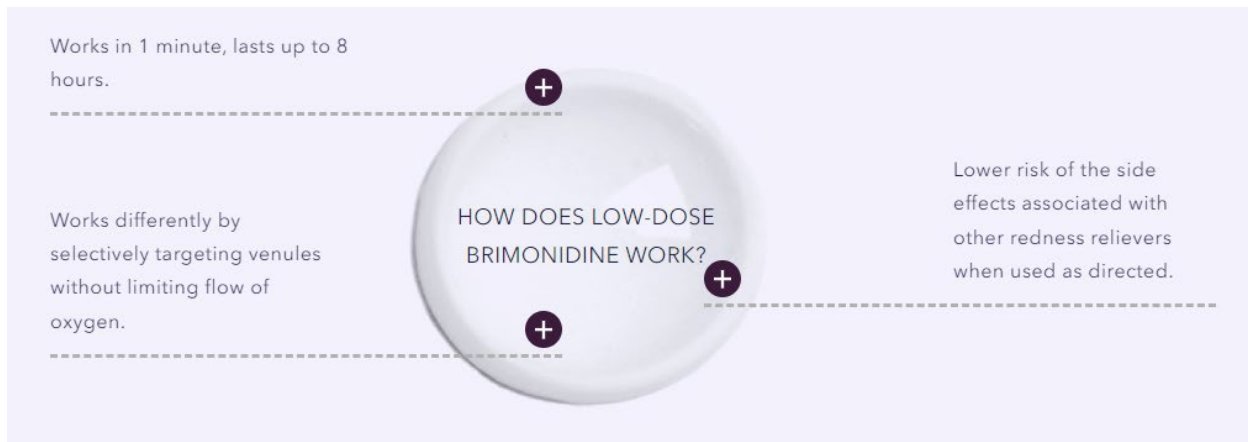
[Learn how brimonidine works](#)

*Low-dose OTC brimonidine

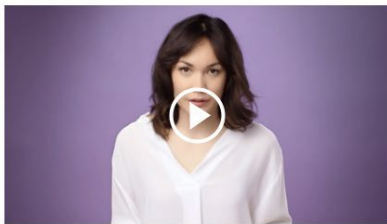
WHAT MAKES EYE DOCTORS CHOOSE LUMIFY?

Before LUMIFY, doctors didn't really recommend redness relieving eye drops because of their known side effects. But LUMIFY is different. Now, eye doctors have a product they can recommend to patients. Doctors like LUMIFY because of the reduced risk of rebound redness and because it uses no bleach or dyes. And it's clinically proven to be safe, effective, and not lose efficacy over time when used as directed. No wonder it's the **#1 eye doctor recommended redness reliever eye drop.**





WANT TO DIG INTO THE SCIENCE OF
LUMIFY EVEN MORE?



WATCH VIDEOS

13. The messaging for ECPs further describes the science behind Lumify and highlights Lumify's uniqueness. For example, below are screenshots from the professional portion of the Lumify website (<https://ecp.lumifyeyes.com/drops/lumify-difference/>), a PDF of which is also provided as EX-2067:



LUMIFY REDNESS RELIEVER EYE DROPS

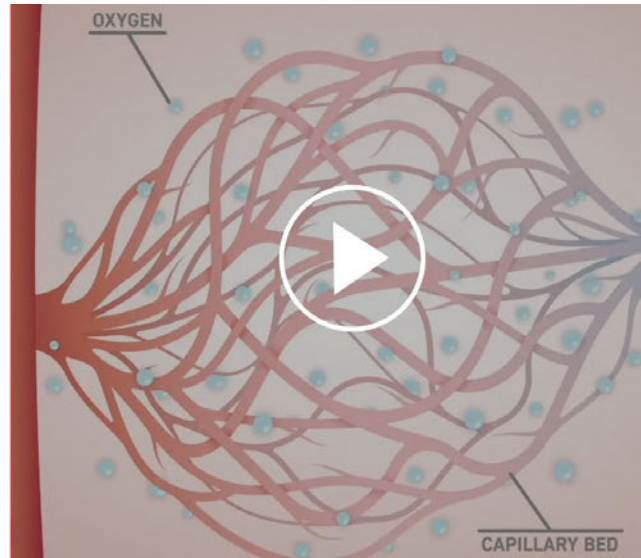
LUMIFY (brimonidine tartrate ophthalmic solution 0.025%) is the first and only over-the-counter (OTC) eye drop developed with low-dose brimonidine tartrate for the treatment of ocular redness due to minor eye irritations.

- Fast-acting and long-lasting efficacy
- A unique method of action for reducing redness[†]
- Low risk for tachyphylaxis or rebound hyperemia when used as directed

[†]LUMIFY is a selective α_2 AR agonist that selectively constricts the venule while maintaining availability of oxygen to surrounding tissue.

SEE HOW LUMIFY WORKS DIFFERENTLY

LUMIFY selectively constricts the venule, alleviating the potential decrease of blood and oxygen flow to surrounding tissue.



HOW LUMIFY COMPARES

LUMIFY with low dose brimonidine tartrate (Selective α_2 -AR agonist)	VS	Other OTC redness relievers (α_1 or α_1/α_2 -AR agonist)
 + No tachyphylaxis and virtually no rebound redness in clinical trials when used as directed + LUMIFY selectively constricts the venule, alleviating the potential decrease of blood and oxygen flow to surrounding tissue		 + Commonly associated with rebound redness and tachyphylaxis + Non-selective vasoconstrictors act on the arteriole, decreasing blood and oxygen flow to surrounding tissue

C. Bausch's Market Research Related to Lumify

14. In order to better understand ECPs' perceptions of Lumify and its competitors on the market, Bausch conducted *awareness and usage* research, which is typical in the pharmaceutical industry. This type of research—and the resulting data generated—is something that Bausch and others in the pharmaceutical industry routinely conduct and rely upon in making strategy decisions and would be generally accepted and relied upon in the industry. Below, I summarize relevant data from

[REDACTED]

[REDACTED]

³ Specifically, these were surveys commissioned by Bausch for market research purposes by Ipsos Healthcare ("Ipsos"). Ipsos is a known, reputable service that

describes itself as “dedicated to understanding the motivations, behavior and influences of the multiple stakeholders driving commercial success in the healthcare industry.” (See EX-2068.) Based on my experience in the industry, surveys like those conducted by Ipsos would be generally accepted and relied upon in the industry. The survey described herein included [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] The complete reports for the two waves of this Attitudes and Usage Study as provided to Bausch are included as EX-2069 and 2070, respectively.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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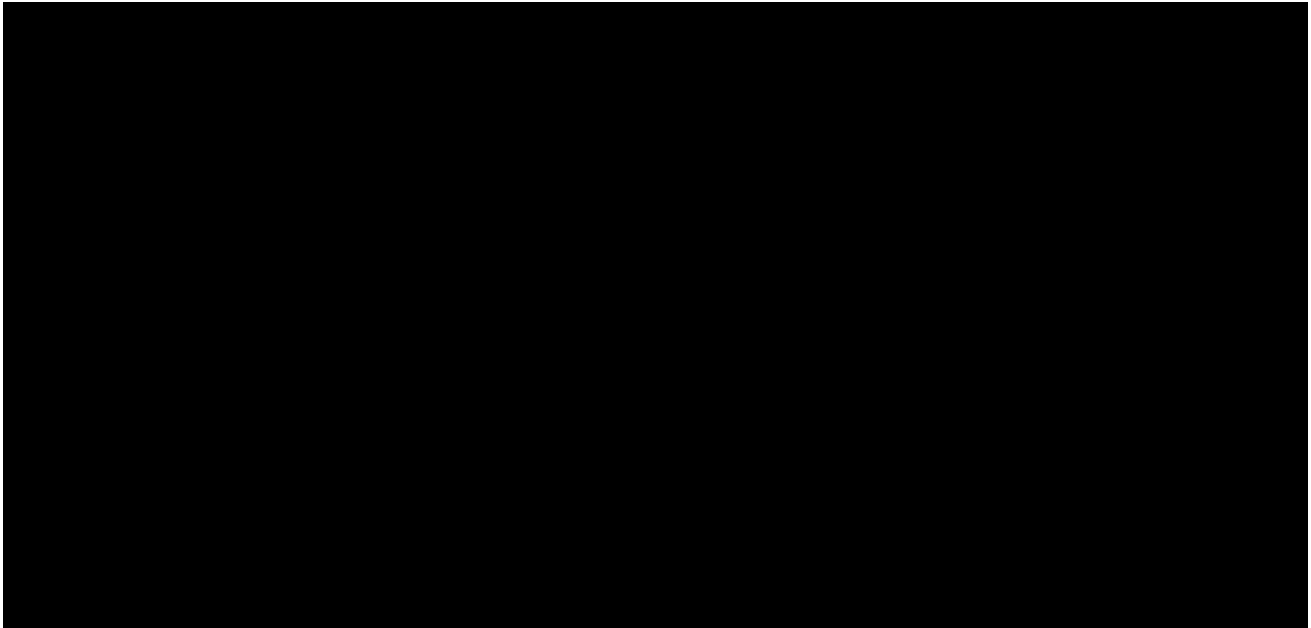
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



20. Overall, these data reflect that the strong performance of Lumify in the marketplace is consistently connected to a number of factors (including its strong performance in relieving redness), all of which are the result of using the unique, low-dose (0.025%) brimonidine formulation.

D. Lumify Is a Key Product for Bausch's Business

21. Lumify eye drops are a *Top 10* product for Bausch, as publicly reported in Bausch's recent Q3 2024 earnings presentation, and Bausch's continued dedication to Lumify's success is clear. (*See, e.g.*, EX-2071 at 23.) Lumify was specifically highlighted in Bausch's earnings presentation as a key franchise. (*See id.* at 5, 7.)

22. In terms of revenue, [REDACTED]
[REDACTED] (*Compare* EX-2063 at 6, 7.) Lumify is a core component of Bausch's revenue. For example, Bausch reported net sales for Lumify in the United States of [REDACTED] in 2023 (EX-2072), which accounts for about [REDACTED] of the entire Vision Care Consumer Product segment. (*Compare* EX-2072 to EX-2073 at 9.) This proportion is expected to continue to grow, as the Lumify product continues to drive its growth and success anchored by its outstanding clinical results. [REDACTED]
[REDACTED]
[REDACTED] EX-2063
at 5.

23. To have the opportunity to commercialize this successful product, Bausch has partnered with Patent Owner, Eye Therapies, and has paid substantial milestones and royalties ([REDACTED] at the time of writing) to Patent Owner. Bausch has also incurred [REDACTED] to date in R&D expenditures related to Lumify.

⁵ This is particularly interesting because Lumify has a higher price point than its competitors—meaning, generally, that a customer is likely to be willing to pay *more* to obtain the superior redness relieving effects of Lumify.

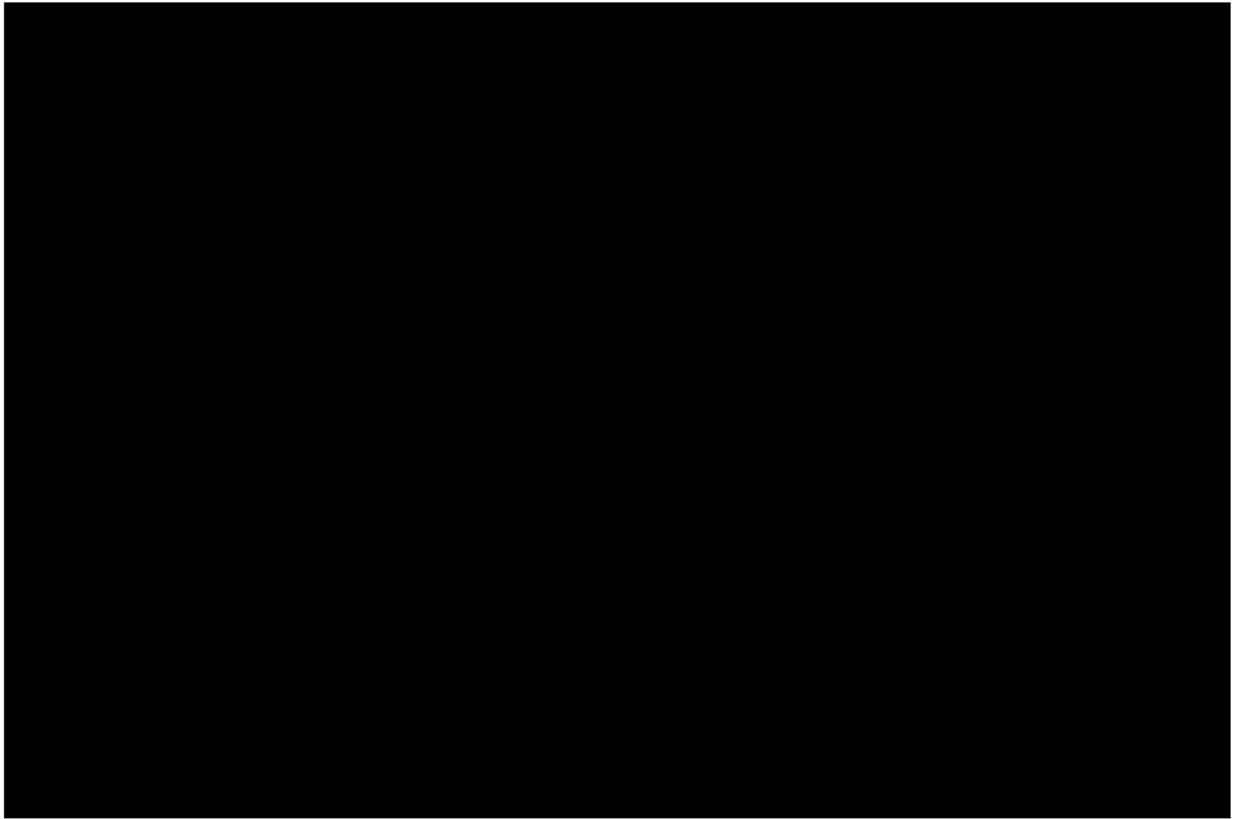
E. Lumify Has Had Extraordinary Market Penetration

24. Lumify's success is demonstrated by Lumify's fast-growing market share in the redness reliever category. For example, Bausch reported publicly in September 2018, that "[w]ithin three months of launching, LUMIFY is already the number one doctor recommended brand of redness reliever eye drops and has already reached a market share of over 20% share of the redness reliever category," based on Circana data (retail dollar share for the week ending Aug. 26, 2018). (EX-2069.) Achieving 20% market penetration within mere *months* of launch was—and continues to be—hugely impressive. This success has continued, with Lumify remaining the number one doctor-recommended redness-relieving drop and obtaining approximately [REDACTED] of weekly dollar market share in this category as of August 2024, despite launching in just 2018. (See EX-2063 at 8.)

25. Much of this growth has been driven by new households entering the redness relief category and strong repeat rates which are both indicators of very strong product performance. In the latest [REDACTED] according to Circana data, [REDACTED] of Lumify users are new to the redness relief category, and [REDACTED] are new to eye care overall. Additionally, [REDACTED] of Lumify purchases are repeated within 52 weeks, which is significantly higher than traditional redness reliever repeat rates. (See EX-2074.) As of June 16, 2024, the number of households purchasing Lumify [REDACTED]. (See EX-2063 at 9.)

26. Lumify's *disruption* of the redness reliever category is clear, as represented in the graph below, which depicts the redness reliever market (with and without Lumify), based on Circana reported retail dollar sales. As shown below,⁶ while the redness reliever market (without Lumify) has stayed relatively flat from 2016 to present, the launch of Lumify in 2018 has changed the trajectory and essentially been the sole driver for growth of the entire category. Based on Circana point-of-sale data, the overall redness reliever marketplace has grown [REDACTED]
[REDACTED]
[REDACTED] but redness relievers other than Lumify have collectively grown [REDACTED]
[REDACTED]
[REDACTED] EX-2075. Lumify has plugged a gap in the market that previously-existing redness relievers could not.

⁶ The graph below was taken from the live Circana database (US all outlets) from the week ending September 8, 2024.



27. Further demonstrating the tangible and unique performance of Lumify, the brand has garnered over [REDACTED] media impressions consisting of unpaid endorsements from media, make-up artists, celebrities and beauty influencers.

28. I understand that certain allegations have been made that the success of Lumify eye drops is because of the magnitude and frequency of Bausch's sales and marketing efforts, rather than borne out of the features of the product itself. In my opinion, this is a red herring—in my experience, it is widely accepted that good marketing cannot save a bad product. It's also widely taught and accepted that highly effective marketing starts with a unique, differentiated product that better

satisfies the wants and needs of consumers. That is what interests consumers in initially purchasing the product and is what causes consumers to keep purchasing the product.

29. Lumify is successful because of its superior clinical results—as is supported by the high rate of repeat buyers as well as additional data. Due to the uniqueness of Lumify, and its unparalleled efficacy and safety as an OTC redness reliever, [REDACTED]

[REDACTED] This indicates product performance is the underlying driver of sales and user satisfaction, not simply “marketing.” [REDACTED]

[REDACTED] EX-2063 at 10. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] as the method of action is distinct and highly differentiated, and thus easily understood, and the benefits are widely recognized by ECPs. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

30. Overall, Lumify is an extremely impressive and successful product, with a unique formulation and outstanding clinical results in redness reduction that have been recognized and rewarded by the eye care industry (both ECPs and consumers), not only in terms of sales, but also in terms of awards, praise, and impressive, continuous growth.

III. DOCUMENTATION AT BAUSCH: MARKET DATA RECORDS

31. As is typical in the pharmaceutical industry, Bausch collects data in several different ways, both internally and externally. In this regard, Bausch collects and relies upon certain established market reports and commercial publications that are generally accepted and relied upon in the industry. For example, Bausch subscribes to a data-collection service provided by a company called Circana, previously known as IRI, a well-known, established company that aggregates otherwise disconnected retail data. (*See* EX-2076 (“IRI and NPD came together in 2023 to become the world’s leading advisor on the complexity of consumer behavior. As Circana™, we set ourselves apart based on three pillars”—the most complete view, unparalleled technology, and deep industry expertise.)) Circana is one of two major data-aggregation sources in the United States—the other being its competitor, Nielsen. Both Circana and Nielsen source data from the same national consumer panel and are considered leaders in the industry due to their reliability.

32. Bausch—like most, if not all, pharmaceutical companies with a retail, over-the-counter business arm—subscribes to Circana. With this subscription, Bausch has access to a variety of data sets, which live in the Circana workspace, available online. Bausch, like all Circana subscribers, can then generate exports of such data, fitting the needs of a particular data request. As one example relevant to this matter, Bausch has access to aggregate data related to the “redness reliever” category of the eyecare market. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] In Circana, while data is saved for years, it is important to keep in mind that there can be things like “restatements” that account for data corrections.

33. Importantly, because the Circana database requires knowledge about both how data is stored, how data is processed, and its user interface, it is important that whoever exports the data is knowledgeable about the workspace; [REDACTED]

[REDACTED]

[REDACTED]

34. Bausch, and in particular the Bausch commercial team, relies upon Circana data in the ordinary course of its business. [REDACTED]

[REDACTED]

[REDACTED] In particular, Bausch relies on two high-level categories of data: *Panel* data and *POS* data. The Circana Panel data are based on projections from a national consumer panel, while the Circana POS data are based on point-of-sale data from retail stores. Panel data is more inclusive of channels—meaning the entire world of consumption (aiming at capturing 100% of total consumption). This data provides a picture of long-term consumption, holistically, but lacks certain details. On the other hand, POS data does not include the entire view of total US data (because it captures a more limited channel of data), but there is a lot more granularity of data. Together, the commercial team and data analysts at Bausch review and rely upon one or both types of data, depending on the purpose of the review. In my role as Executive Vice President, US/Canada Consumer, my team regularly relies on Circana data and considers the Circana data to be a reliable compilation of market data—in fact, I have a particular expertise with this data, as I previously worked at Circana.

35. The spreadsheet at LUMIFY LEGAL DATA OCTOBER 2024 (hereinafter, “Circana Panel Data”) (EX-2077) is an authentic export of Circana panel data. It includes the US geography, including all outlets (which includes total brick-and-mortar and online sales). It includes the overarching redness reduction category [REDACTED] as well as the individual

major branded products within the redness reduction category. This is an example of Circana data on which Bausch regularly relies. It comes from “living” data updated at Circana and was provided by an employee or representative of Bausch with knowledge of the database. In the regular course of Bausch’s business, Bausch exports and relies on these types of data, and in the regular course of Bausch’s business, Bausch keeps and updates these records. The Circana Panel Data is a true and correct copy of the exported Panel Data, as of June 8, 2024, and accurately reflects the data provided by Circana, to the best of the company’s knowledge.

36. The spreadsheet at LUMIFY LEGAL DATA POS OCTOBER 2024 (hereinafter, “Circana POS Data”) (EX-2078) is an authentic export of Circana data. It includes the US geography, including multiple outlets (which includes the food channel, drug channel, mass channel, and selected club retailers, excluding online-exclusive sales (meaning bought online and delivered to home)). It includes the overarching redness reduction category, as well as the individual products within the redness reduction category. The revenues and prices in the Circana POS data generally reflect what consumers pay at the register. Units captured in the Circana POS data refer to packages (such that, for example, one package with two bottles would be captured as one unit) while volume in the Circana POS data is in fluid ounces. Additionally, the “Price per Unit” measure is closer to net price (i.e., price paid by customer at the register after any promotions/discounts/coupons have been

applied) while the “Price per Unit No Merch” measure is closer to gross price (i.e., without any promotions/discounts/coupons applied); therefore, the “Price per Unit No Merch” price may be higher than the price per unit, in light of promotions that may have lowered the sales price. This is an example of Circana data on which Bausch regularly relies. It comes from “living” data updated at Circana and was provided by an employee or representative of Bausch with knowledge of the database. In the regular course of Bausch’s business, Bausch exports and relies on these types of data, and in the regular course of Bausch’s business, Bausch keeps and updates these records. The Circana POS Data is a true and correct copy of the exported POS data, as of September 29, 2024, and accurately reflects the data provided by Circana, to the best of the company’s knowledge.

37. The spreadsheets LUMIFY INCREMENTALITY 09-08-24 (EX-2075) and LUMIFY INCREMENTAL TO EYE CARE AND RED RELIEVERS CATEGORY 11-03-24 (EX-2074) are authentic exports of Circana data. These are additional examples of Circana data on which Bausch regularly relies. They come from “living” data updated at Circana and were provided by an employee or representative of Bausch with knowledge of the database. In the regular course of Bausch’s business, Bausch exports and relies on these types of data, and in the regular course of Bausch’s business, Bausch keeps and updates these records. The Circana data is a true and correct copy of the exported incrementality and

incremental to eye care and red relievers data, as of the dates captured in the documents, and accurately reflects the data provided by Circana, to the best of the company's knowledge.

I declare that all statements made herein of my knowledge are true, that all statements made herein on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Executed on December 2, 2024.

/John Ferris/
John Ferris
Executive Vice President,
US/Canada Consumer
Bausch + Lomb